



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,157	02/27/2002	Nissim Garti	1662/56302	2652

26646 7590 05/27/2003

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 05/27/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/086157

Applicant(s)

Ganti et al

Examiner

J. D. Ford

Group Art Unit

1624

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- ☐ Responsive to communication(s) filed on 4-21-03 and 4-30-03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-16, 26-31, 42-61, 67-71 and 77-153 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-16, 26-31, 42-61, 67-71, and 77-153 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
  - ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1624

The response of 4/21-03 was followed by a supplemental response of 4-30-03.

We are now up to claim 153.

Consider claims 151-153. Lamotrigine need be recited as an IUPAC <sup>name</sup> ~~the~~ USPTO records are kept in the IUPAC system, not ~~by~~ common name. Claims need be complete within themselves, it is not ~~proper~~ to refer to Fig. 15, within(a) claim. Form Q <sup>or</sup> ~~form O~~ tells the reader nothing in claim 149 or claim 144. Try combining claims 149-153 in the same claim, with all the data. Claims 150 and 151 appear contradictory. Both recite the supposed peaks, but they are different. The form of claims 124-153 are rejected, as noted in the discussion above. No one knows in claim 124 what form E is. Claims 125 and 126 say different things, both said to be X-ray powder diffraction patterns for Form E, yet contradictory. Applicants need to use IUPAC names, rather than Lamotrigine, the same compound could be in the records, but under <sup>a</sup> different name. Try combining the information of claims 124--128 in the same claim, with all the data.

Claims 124--153 are, therefore, not clear, and do not rise to the requirements of 35 U.S.C. 112, 2nd paragraph.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph, IUPAC names ~~must~~ be used to search the records. What crystalline form is being claimed? Some crystalline Forms are known. What is the structure of the solvate claimed?

In regard to claims 92 and 93 one has no way of knowing that is not in the prior art.  
Inherent; 35 U.S.C. 102.

Art Unit: 1624

Claims 117--123 are rejected under 35 U.S.C. 112, 2nd paragraph, as one has no way of knowing what is being prepared. In claim 117, is the lamotrigine solvate, being heated, part of the prior art? What is the source of the starting materials? What is the starting material?

If the subject of this application is reg# 84057-84-1, the claims do not appear to distinguish therefrom. No forms, different from what is known, are established. No one claim adequately describes a new crystalline form, or is persuasive that the form does not exist in the prior art.

Claims 2--16 are rejected under 35 U.S.C. 112, 2nd paragraph. It would require combining claims 2--6 in one claim to begin to set forth what form B is. *claims 2--16* are rejected for the reasons noted in the previous Office Action.

Page 4, last paragraph of the most recent response appears to indicate Form E1 was canceled, but claim 26 is still present. Form E1 is still in claims 129--133.

Claim 26 is dependent on canceled claim 22.

Claims 27--31 would have to be combined into one claim to begin to describe a crystalline form, but is it new?

Same, with form K, L, N, N, P, R, S, U, what are they? Are they not in the prior art?

Is the lamotrigine anhydrate of claims 94--116, known? What is being prepared form what?

Claims 1--16, 26--31, 42--61, 67--71, 77-93 and 124--153 are said to be different crystalline forms of something called lamotrigine, said to a known compound. No additional

Art Unit: 1624

property is seen alleged. No physical melting point difference is seen alleged. No utility variation is seen alleged. No reason is seen established to not believe that the forms alleged are not inherent in the known material. Accordingly, these claims are rejected under 35 U.S.C. 102 over the known material. Where is the statutory new, useful and unobvious? What is known? Are these forms stable on long standing? What industrial applicability do these form have, that the compounds that are known do not have. Generally when something is allowed, it is better than the prior art at something. Is that present here? The new alleged material, minimally must be established as different. That is not seen to have been done here. (35 USC 101)

What is the structure of what is being claimed? If it no different than the known compound, how have applicants brought into existence anything different that what is known?

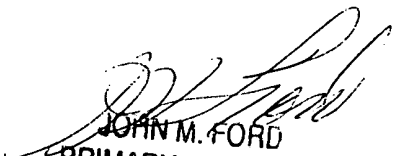
A detailed product-by-process claim, with X-ray diffraction data in one claim for each form is suggested.

No reference to a drawing will be permitted in a claim, Words can describe <sup>h</sup>were the peaks are.

IUPAC names are necessary to know what other compounds of the same structure are known, Common names are not acceptable. The USPTO uses IUPAC names to catalog the prior art.

John M. Ford:jmr

May 22, 2003

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624